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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,557	08/16/2000	Brydon L. Bennett	860098.436	6892

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

18

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/642,557

Applicant(s)

BENNETT ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____ .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 25-31 and 33 is/are allowed.
- 6) ☒ Claim(s) 9, 24 and 39 is/are rejected.
- 7) ☒ Claim(s) 17-23, 32 and 34-38 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15 .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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DETAILED ACTION

This is a response to Applicant's remarks filed 12-18-02. Claims 10-16 have been canceled. Claims 1-3, 8, 9, and 17-19 have been amended. Claims 1-9 and 17-39 are pending in this application.

The objection to claims 1-23 for containing non-elected subject matter has been overcome with Applicant's amendments. The rejections of claims 1-4 and 8 under 35 U.S.C. 102 and 103 have been overcome with Applicant's amendments. The rejection of claim 9 under 35 U.S.C. 112 has been maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24 is rejected under 35 U.S.C. 102(b) as being anticipated by STN

International® CAPLUS Database, Accession No. 1989:185177, Showalter et al..

Applicant claims a composition comprising an anthra[1,9-cd]pyrazol-6(2H)-one compound or a pharmaceutically acceptable salt thereof.

Showalter et al. teach an anthra[1,9-cd]pyrazol-6(2H)-one compound which is useful as an antitumor agent. Showalter et al. teach that compositions of the compound may be prepared since the compound of Showalter et al. has a pharmaceutical use.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 9 is directed to “a method for treating a condition responsive to JNK inhibition”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There are a vast number of conditions responsive to JNK

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inhibition and Applicant does not give support for "treating" all forms of these disorders. The level of ordinary skill in the art is high. The art pertaining to conditions responsive to JNK inhibition remains highly unpredictable. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Applicant provides limited working examples which do not embrace the scope of the claims. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that applicants incorporate the conditions in claims 10-16 into claim 9 in order to obviate the rejection under 35 U.S.C. 112 first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 is drawn to "a composition comprising JNK". The meaning of this phrase is unclear. In the specification, on page 6, line 13, Applicant describes the instant invention as being directed to "compounds having activity as selective inhibitors of JNK". Therefore, it is unclear how Applicant's invention can also be directed to "a composition comprising JNK." Appropriate correction is requested.

Claim Objections

Claim 39 is objected to because of the following informalities: Claim 39 is drawn to two statutory classes of inventions: compositions and compounds. It is requested that Applicant limit claim 39 to one statutory class of invention. Appropriate correction is required.

Claims 17-23, 32, and 34-38 are objected to as being dependent upon a rejected base claim.

Allowable Subject Matter

Claim 1-8, 25-31 and 33 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments filed 12-18-02 have been fully considered and have been found persuasive regarding Applicant's submission that claim 24 must be examined in the present application.

Applicant's arguments regarding the rejection of claim 9 under 35 U.S.C. 112 have been fully considered but they are not persuasive. Regarding the rejection of claim 9, under 35 U.S.C. 112, Applicant argues that the specification fully enables a method for inhibiting JNK *in vivo* for the following reasons (1) the specification teaches that the compound of the invention inhibit JNK; (2) the specification teaches pharmaceutical compositions comprising a compound of the invention; (3) the specification teaches how to administer a compound of the invention or a pharmaceutical composition containing a compound of the invention to a patient in need

thereof; and (4) the specification provides animal model data showing the beneficial effects resulting from the administration of a JNK inhibitor with respect to several unrelated disorders. However, these teachings in the specification are general and they do not embrace the full scope of the claim. Example 8 beginning on page 50 shows the activity of representative compound, however, the biological studies described are limited. Undue experimentation would be required to use the instant compound as claimed in claim 9 because there are a plethora of diseases which are responsive to JNK inhibition. The limited assays in Applicant's specification do not support that Applicant's compound is useful in treating any and all conditions responsive to JNK inhibition. It is suggested that Applicant incorporate the conditions in the claim which are supported in the specification as being treatable by *in vivo* inhibition of JNK.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for

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draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

February 28, 2003